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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,156	06/04/2001	Akira Tanaka	107380-00005	8786

7590

01/10/2003

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,156

Applicant(s)

TANAKA ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 139 is/are pending in the application.
- 4a) Of the above claim(s) 2,7 and 15-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

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Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 11 is acknowledged. Applicant further made election of Group III; however, it is noted that the first line of the restriction requires the election of one of the following. Further, applicant's attempt at electing two groups is not clear because applicant states that the examiner indicated that "the product claim will be examined with the elected method use" but no method of use was elected, e.g., the elected Group I is the product and Group III is drawn to a method of making. Further, it is noted that the office action stated that the product will be examined with the elected invention; however, the elected invention herein is the product. Additionally, the process of making the compounds in Group III are distinct, as such compounds may be made by materially different methods, such as, halogen exchange, tributyltin substitution etc. The election of the product is further supported by applicant's election of the species of claim 14. Claim 2 and 7 are withdrawn as not being directed to the elected species. Claims 15-39 are withdrawn as not being drawn to the elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6 and 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wester et al. (J Nucl. Med., 1999, PTO-1449) in view of Coenen (US 4,925,651) and Tomiyoshi (Nucl. Med. Comm., 1997, PTO-1449).

Webster discloses the compound O-(2-[¹⁸F]fluoroethyl)-L-tyrosine for PET imaging, see abstract and figure 1, page 206. The compound was formed in both the L- and D- form and mixtures thereof, see abstract and page 207, column 1.

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Wester discloses a compound that is very similar to those encompassed by the instant claims. For example, the compound disclosed by Wester only differs from those claimed in that the tyrosine is not methyltyrosine, as well as, with regard to the elected species, by only an additional -CH₂- group in the fluoroalkyl substitution (e.g., ethyl as compared to propyl of the elected species). Further, Wester fails to specifically disclose the various isomers, as claimed.

However, it is well known in the art that tyrosine and methyltyrosine are structurally obvious analogous compounds that are functionally equivalent, as shown by Coenen and Tomiyoshi.

Coenen discloses F-18 or I-123 labeled tyrosine compounds that are both structurally analogous and have the same utility as those disclosed by Wester (i.e., PET imaging), see abstract. Coenen teaches that such compounds may have either a hydrogen (i.e., tyrosine) or a methyl group (methyltyrosine) as equivalent substitutions, i.e., that tyrosine and methyltyrosine are functionally equivalent, see column 2, lines 11-35 and claims 3 and 4.

Tomiyoshi teaches that 18F-methyltyrosine is a useful radiopharmaceutical for PET imaging. Tomiyoshi also teaches that ortho- and meta- substituted methyltyrosine isomers may be prepared, see figure 7, page 18.

It would have been obvious to one of ordinary skill in the art to have modified the compound -(2-[18F]fluoroethyl)-L-tyrosine disclosed by Wester to be -(2-[18F]fluoroethyl)-L-methyltyrosine, by replacing hydrogen with a methyl group because it is known in the art that methyltyrosine is effective for the same utility and is functionally equivalent to tyrosine in analogous compounds, as shown by Coenen and/or Tomiyoshi. Further, the substitution of a methyl group for a hydrogen is known in the art to be a structurally obvious modification to gain the advantage of obtaining analogous chemically related compounds. For example, see *In re Wood*, 82 F.2d 638, 199 USPQ 137 (CCPA 1978). Such structural obviousness is supported by the teachings of Coenen and Tomiyoshi, which teach tyrosine and/or methyltyrosine compounds as equivalents useful in PET imaging. Also the addition of a single -CH₂- group in a chain, for example, to arrive at applicant's elected species, by changing the fluoroethyl of Wester to a fluoropropyl group, is also structurally obvious to gain the advantage of providing chemically related analogs that would be expected to have similar properties by the chemist having ordinary skill in

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the art, for example, see *In re Henze*, 181 F.2d 196, 200-01, 85 USPQ 261, 264 (CCPA 1950). Further, it would have been obvious to one of ordinary skill in the art to prepare various isomeric forms and/or racemic mixtures thereof, to obtain position isomers and racemic forms, which are structurally obvious analogues that are expected to have equivalent uses and similar properties, for example, see *In re Crounse*, 363 F.2d 1390, 150 USPQ 554 (CCPA 1966). Both Wester and Tomiyoshi support the structural obviousness of isomers, by teaching that the compounds may include various isomeric forms thereof.

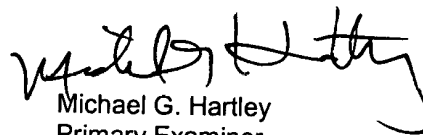
Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
January 9, 2003